Please amend claim 4 as follows.

4. (Amended) A vaccine as in claim 1, wherein the immunogen is an inactivated cell line which expresses [expressed] FIV antigens.

Please cancel claim 9.

REMARKS

Claims 1-10 were examined, with claims 11-13 having been previously cancelled. Claims 1 and 4 have been amended. Claims 3 and 9 have been cancelled. Reexamination and reconsideration of the claims, as amended, are respectfully requested.

Applicants acknowledge the provisional obviousness-type double patenting rejection. Copending application serial no. 07/726,061, has not yet been allowed. Applicants will file an appropriate Terminal Declaimer on the latter-issued of the two copending cases.

Claims 3 and 9 were rejected under 35 U.S.C. § 101 for lack of utility. Without conceding the appropriateness of this rejection, applicants have cancelled claims 3 and 9 to expedite prosecution of the present application.

Claims 1-10 were rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness. Applicants have amended the claims as suggested by the Examiner and thus believe that this rejection has now been overcome.

Claims 3 and 9 were also rejected under 35 U.S.C. § 112, first paragraph, for lack of enablement. Again, without conceding the appropriateness of this rejection, applicants have cancelled claims 3 and 9, rendering the rejection moot.

The only remaining rejection is stated under 35 U.S.C. § 112, first paragraph, for enablement. The Examiner contends that claims 1, 2, 4-8, and 10, are enabled only for claims limited to "a vaccine protective against FIV-Petaluma and FIV-Dixon, wherein the immunogen is inactivated whole FIV-Petaluma or an inactivated cell line which expresses antigens of such an FIV strain." Such rejection is respectfully traversed.

The Examiner relies on MPEP Sections 706.03(n) and (z). Taken together, these sections set forth what is generally referred to as "undue breadth" rejections. The Examiner specifically states that the "disclosure is not enabling for the production and use of a vaccine protective against other strains of FIV (*i*.e., Maryland and Japanese strains of FIV which differ from FIV-Petaluma by 21-22% in outer envelope amino acid sequences...), or which comprises FIV immunogens other than inactivated FIV-Petaluma-infected cell lines or inactivated, whole Petaluma...." Such rejection is respectfully traversed for the following reasons.

Applicants believe that the disclosure of the present application sufficiently enables the preparation of vaccines against any and all strains of FIV. The specification includes specific techniques for obtaining and inactivating whole viruses and/or obtaining inactivated cell lines which express FIV antigens. The fact that working examples have not been provided for each and every strain of FIV is irrelevant. Since the vaccine preparation methods have been effective for all FIV strains tested, there is no reason to believe that they would not be effective for other known and unknown FIV strains.

The Examiner also seems to require a showing that a single FIV strain be cross-protective against all other existent strains of FIV. Applicants will concede that such a showing has not been made, and will even further concede that such a showing may never be made. This lack, however, does not mean that

applicants have failed to support the broadest claims in the present application. Claim 1 merely sets forth a vaccine which comprises an immunogen which is protective against FIV infection when administered to a host. The claim does not set forth that it is protective against all possible sources of FIV infection. Applicants believe that the fact that they teach methods sufficient to provide vaccines against any given strain should be sufficient to support claim 1.

Applicants, however, have gone well beyond this minimum showing. In the previously submitted declaration of Dr. Janet Yamamoto, it is shown that protection against heterologous challenge can be achieved even when the protective strain and challenging strain differ by as much as 11% in the external envelope sequences. While it has not yet been demonstrated that protection against heterologous challenge can be achieved with even wider sequence variations, such a showing should not be required to support the claims presently in this application.

The Examiner's position leads to untenable results. The Examiner must recognize that the inventors herein were the first to discover FIV and the first to establish that vaccines can be prepared against FIV infection. To the extent that FIV is analogous to HIV, the Examiner can appreciate the great significance of this demonstration. The Examiner, however, would limit the claims to the particular strains which have been utilized in the working examples since the applicants have not yet shown effectiveness with all strains and cross-reactivity with all other strains. Such a result is unacceptable.

The courts have recognized that broad claims should issue commensurate with the nature and scope of an invention. See, *e.g.*, *In re Hogan*, 194 U.S.P.Q. 527 (CCPA 1977), where it is recognized that unduly restricting the right of an inventor to a generic claim would jeopardize the rights of an inventor of basic and pioneering inventions and discourage the early disclosure of

such inventions. The present case, as the discoverers of the virus and the first to demonstrate the ability to produce a vaccine against the virus, applicants are clearly entitled to claims of the scope presently in the application.

In view of the above amendments and remarks, applicants respectfully submit that all claims remaining in the application are now in condition for allowance and request that the application be passed to issue at an early date.

If for any reason the Examiner believes that a telephone conference would in any way expedite prosecution of the subject application, the Examiner is invited to telephone the undersigned at (415) 326-2400.

Respectfully submitted

TOWNSEND and TOWNSEND KHOURIE and CREW

Date: 2/11/93

James M. Heslin, Reg. No. 29,541

TOWNSEND and TOWNSEND KHOURIE and CREW
One Market Plaza
Steuart Street Tower
20th Floor
San Francisco, California 94105
(415) 326-2400

JMH:kit